

U.S. Patent Application Serial No. 10/724,663  
Amendment dated May 1, 2007  
Reply to Office Action of March 7, 2007

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### REMARKS

This paper is filed in response to the Office Action mailed March 7, 2007 regarding the above-referenced Application. Claims 1-16 were pending in the application. In the Office Action claims 1-16 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,423,758, issued to Shaw (hereinafter "Shaw"). Claims 1-16 were also rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,487,732, issued to Jeffrey (hereinafter "Jeffrey").

By this Amendment and Response, claims 1, 4, 8 and 9 have been amended and claim 10 has been cancelled. New claims 17 and 18 have been added. Exemplary support for the amendment to claims 1 and 4 can be found in Figures 7A-7C and paragraph [0073] of the Present Application. Exemplary support for the amendment to claim 8 can be found in Figures 7A-7C, paragraphs [0073] and [0077] and the text of cancelled claim 10. Exemplary support for the amendment to claim 9 can be found in paragraph [0073]. Exemplary support for new claims 17 and 18 can be found in Figures 7A-9 and in paragraph [0077]. Therefore, no new matter has been added. Reconsideration of claims 1-9 and 11-18 is respectfully requested.

Applicants would like to thank Examiner DeSanto for the interview conducted on March 22, 2007 with Applicants' representatives Kevin Laurence and Matthew Bethards. Independent claims 1, 4 and 8 were discussed in view of Shaw and Jeffrey. The Examiner agreed that the amendments proposed above and arguments presented herein would distinguish the claims over both Shaw and Jeffrey.

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### **Claim Rejections – 35 USC § 102**

#### **Shaw (U.S. Patent No. 5,423,758)**

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw. See Office Action, page 2. The Applicants respectfully traverse this rejection.

It is well settled that a claim is anticipated under 35 U.S.C. § 102 only if “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” MPEP §2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-7 and 18 all claim a method for providing an injection from a medical device, and claims 8-17 all claim a medical device for providing an injection of fluid. This is not taught or disclosed by Shaw, and as such, Shaw does not anticipate these claims under §102(e). Shaw does not disclose a device or method for delivering fluid, but rather “an automatically retractable fluid collecting device.” See Shaw, abstract.

For example, claims 1-7 and 18 include the step of providing a cartridge containing a quantity of medicinal fluid. Claims 8-17 include the element of an ampoule of fluid. Shaw discloses an empty or evacuated collection tube (72). See Shaw, col. 7, line 13. The device disclosed in Shaw performs the function of *removing* fluid from a patient, while conversely, the pending claims are directed to *delivering* fluid to a patient. Therefore, Shaw is not an anticipatory reference.

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Furthermore, claims 1-3 and 18 include the element of the mounting stem extending longitudinally within the barrel along a majority of a length of the barrel. There is no structure disclosed in Shaw that meets this element as well as the other structural features of the claimed mounting stem. For example, needle holder (20) of Shaw does not extend along a majority of a length of the barrel. Consequently, for this additional reason claims 1-3 and 18 are not anticipated by Shaw.

Moreover, claims 4-7 include the element of retaining the seal in a fixed axial position relative to the barrel while displacing the fluid container forwardly over the seal to expel fluid. Shaw does not disclose such an element. The cartridge (72) of Shaw is not displaced relative to the diaphragm (74) and fluid is not expelled. Accordingly, Shaw does not anticipate claims 4-7.

Additionally, claims 8-17 recite "provid[ing] and injection of fluid...by displacing the ampoule forwardly relative to the stem" and "a second radial member disposed in a proximal portion of the housing...maintaining the stem aligned parallel with the axis of the housing." Shaw does not disclose either of these elements. Shaw does not provide an injection of fluid, but instead draws fluid, and it does not accomplish this by displacing the cartridge (72). Furthermore, Shaw does not have a second radial member at a proximal portion of the housing, because there is no structure that could conceivably be construed to constitute a mounting stem that extends to the proximal portion of the housing. Therefore, Shaw does not anticipate claims 8-17.

In view of the foregoing, Applicants respectfully request the rejection under Shaw be withdrawn.

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Jeffrey (U.S. Patent No. 5,487,732)

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeffrey. See Office Action, page 3. Applicants respectfully traverse this rejection.

As discussed above, a claim is only anticipated if a prior art reference discloses each and every element of the claim. MPEP §2131. Claims 1-3 and 18 include the element of a mounting stem extending longitudinally within the barrel along a majority of a length of the barrel. Jeffrey discloses a needle holder (24); however, the needle holder does not extend along a majority of a length of the barrel. Furthermore, claims 1-3 and 18 including the element of "displacing the fluid container forwardly through the annular passage." Jeffrey does not teach this element. Instead Jeffrey teaches movement of the plunger (30) and not the cartridge (50). See Jeffrey, Figs 2-3. Consequently, the disclosure of Jeffrey does not anticipate claims 1-3 and 18.

Claims 4-7 include the element of "displacing the fluid container forwardly over the seal to expel the fluid." Jeffrey does not disclose this element. Instead, Jeffrey teaches movement of the plunger (30) and not the cartridge (50). Furthermore, the cartridge (50) of Jeffrey is not displaceable over the septum (58). In addition, the radial member attached to the mounting stem recited in claims 4-7 cannot be read onto the extension arms (42) of Jeffrey because the extension arms engage a recess in the plunger (30), but not the barrel from which the needle extends. Since Jeffrey does not disclose each and every element of claims 4-7, Jeffrey does not anticipate claims 4-7.

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Claims 8-17 recite a first radial member disposed in a distal portion of the housing and a second radial member disposed in a proximal portion of the housing. Both radial members cooperate with the mounting stem as recited in the claims. Jeffrey does not disclose first and second radial members at distal and proximal portions of the housing, respectively. Moreover, there are no radial members in Jeffrey on both the distal and proximal portions which cooperate with a mounting stem as recited in claims 8-17.

Additionally, claims 8-17 recite "displacing the ampoule forwardly relative to the stem." As discussed above, Jeffrey does not teach this element because Jeffrey discloses movement of the plunger (30) and not the cartridge (50). Moreover, Jeffrey does not disclose that "continued forward displacement of the ampoule operates to effectuate release of the needle" as recited in claims 8-17. Instead, it is the forward movement of the plunger (30) of Jeffrey that effects release of the needle holder (24). Since Jeffrey does not teach each and every element of claims 8-17, Jeffrey is not anticipatory prior art.

In view of the foregoing, Applicants respectfully request the rejection under Jeffrey be withdrawn.

In light of the amendments and arguments presented herein, Applicants submit that the claims define patentable subject matter and a Notice of Allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the telephone number given herein.

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address: (Customer No. 26,152).

Specialized Health Products, Inc.  
c/o Intellevate  
P.O. Box 52050  
Minneapolis, MN 55402

DATED this 1<sup>ST</sup> day of MAY, 2007.

Respectfully submitted,



Kevin B. Laurence  
Attorney for Applicant  
Registration No. 38,219

STOEL RIVES LLP  
One Utah Center  
201 South Main Street, Suite 1100  
Salt Lake City, Utah 84111  
Telephone: (801) 578-6932  
Facsimile: (801) 578-6999